UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al. ex rel.* DAVID KESTER, Plaintiffs, - v - NOVARTIS PHARMACEUTICALS CORPORATION, *et al.*, Defendants.	:	11 Civ. 8196 (CM)(JMF) ECF Case

MEMORANDUM OF LAW OF THE UNITED STATES IN OPPOSITION TO NOVARTIS'S MOTION TO COMPEL

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Plaintiff the United States ("Government"), by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, respectfully submits this memorandum of law in opposition to defendant Novartis Pharmaceutical Corporation's ("Novartis") motion to compel dated September 10, 2014 ("NPC Br."). [Dkt. 246]. For the reasons set forth below, Novartis's motion to compel should be denied insofar as it pertains to the Government.

PRELIMINARY STATEMENT

The Government intervened in this action because investigation showed that, in an effort to increase drug sales, Novartis gave specialty pharmacies kickbacks to induce the pharmacies to recommend two of its brand-name drugs, Myfortic and Exjade. Specifically, Novartis paid rebates to numerous pharmacies in return for making recommendations to switch patients to Myfortic from competitor drugs, and it also gave BioScrip, Inc., another specialty pharmacy, patient referrals and rebates in exchange for recommending refills to Exjade patients under the guise of "patient education" and "counseling."[1] By giving pharmacies remuneration in return for recommendations, Novartis violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"), and caused the pharmacies to submit false claims to Medicare and Medicaid in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq*. ("FCA").

In accordance with its discovery obligations, the Government has produced several hundred thousand pages of documents and large collections of claims data. On the other hand, insofar as Novartis has sought improbably broad discovery from many federal agencies without explaining their relevance, the Government has objected to such requests because there is no basis for believing they are relevant to this case. If anything, Novartis's motion underscores why the Government need not respond to those overbroad requests.

"[T]he burden of demonstrating relevance is on the party seeking discovery." *Freedman*

[1] In January 2014, BioScrip settled with the Government and the States, giving extensive factual stipulations and paying, based on its financial condition, $15 million over time. [Dkt. 41].

v. Weatherford Intern., 2014 WL 3767034, at *3 (S.D.N.Y. July 25, 2014) (*Francis, J.*). Here, Novartis has failed to make this showing. Its motion starts with a false premise — instead of justifying its requests in terms of the legal standards from Judge McMahon's prior decisions and the Government's allegations, Novartis's selective summary of the "relevant legal and factual background," offers a distorted version of both. *See* NPC Br. at 4-8. It fails to mention, let alone discuss, prior decisions that bear directly on this motion. *See infra* at 3-4, 7-8. Further, contrary to Novartis's suggestion, the Government is not alleging that the Exjade scheme violated the AKS and FCA because it did not meet some "industry standard" for adherence, but because Novartis gave BioScrip kickbacks to recommend Exjade refills. *See infra* at 5-6.

Under the relevant legal standards and the actual allegations, Novartis cannot show any "necessary connection" between its requests and the claims and defenses in this case. *First*, while Novartis seek discovery into a wide range of federal programs or policies relating in any way to medication adherence, it fails to show the relevance of these "adherence-related" requests. Specifically, Novartis does not, and cannot, point to any authority to support its legal theory that how federal programs deal with medication adherence sheds light on whether relationships between drug-makers and pharmacies comply with the AKS. *See infra* Pt. II.A. Novartis also fails to identify any meaningful similarity between the federal programs and its Exjade scheme. In fact, as public information shows, the only program referenced in its brief (the Medication Therapy Management program under Medicare Part D) is fundamentally different. *See id*. Novartis's back-up argument for the "adherence" requests – that the internal workings of federal programs somehow shed light on Novartis's knowledge or intent – is equally meritless. Whether a FCA defendant acted knowingly is about that defendant's *own* knowledge. Thus, a defendant like Novartis is not entitled to discovery about matters that did not factor into its decision-making just to create *post hoc* justifications. *See infra* Pt. II.B.

Second, Novartis also cannot justify the relevance of its demand for clinical protocols

from federal health facilities. It claims that such information is relevant because it can show that recommendations to physicians and patients from pharmacies receiving kickbacks were clinically acceptable or did not in fact influence anyone. *See* NPC Br. at 16-20. This is an ill-disguised attempt by Novartis to resurrect an argument – FCA liability depends on whether the pharmacies getting kickbacks succeeded in "convinc[ing] a physician to … prescribe a drug that he would not have otherwise prescribed, or convinc[ing] a patient … to order a refill he would not have otherwise ordered" – that Judge McMahon already rejected. Instead, the Court held that "it is the kickback arrangement itself that constitutes the AKS violation," and that the "illegal recommendations [] do not have to actually convince someone to purchase the drugs who would not have otherwise done so." *Novartis I* at 34. Allowing discovery into the clinical protocols of federal health facilities, thus, would be an exercise in irrelevance. *See infra* Pt. III.[2]

Finally, the discovery sought by Novartis not only has no relevance, responding to its requests will be highly burdensome. Because Novartis cannot articulate a plausible standard for relevance, it would put a heavy burden on numerous federal agencies and facilities to sift through reams of information in an effort to divine what *might* be deemed relevant. There is simply no basis to impose such a burden on the Government, and the Court also should deny Novartis's motion pursuant to Rule 26(b)(2)(C) because the burden associated with responding to those requests outweighs their likely benefit to the adjudication of this case. *See infra* Pt. IV.

RELEVANT BACKGROUND

A. Contrary to Novartis's Suggestion, It Had Ample Notice That the Anti-Kickback Statute Proscribes Using Kickbacks to Improperly Influence Pharmacy Staff

Congress enacted the AKS out of concern about the harms to Medicare, Medicaid, and other federal healthcare programs from the payment of kickbacks, in whatever form, to those

[2] Insofar as Novartis's motion pertains to its demand for communication between BioScrip and the Government regarding certain factual stipulations, NPC Br. at 21-24, the Government has produced those and, as Novartis acknowledged, that aspect of the motion is moot. [Dkt. 269].

who can influence health care decisions. *See United States v. Ruttenberg*, 625 F.2d 173, 177 (7th Cir. 1980). The AKS makes it illegal for (*i*) "*whoever* knowingly and willfully solicit[] or receive[] any remuneration in return" for either "referring an individual … for the furnishing ... of any item or service" or "purchasing, leasing, ordering, or arranging for or recommending" the purchase or order of "any good, facility, service, or item" covered by the Government; and (*ii*) any entity or individual to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) . . . to *any person* to induce such person . . . to purchase, . . . order, . . . or recommend purchasing … or ordering any good . . . or item" that is covered by the Government. 42 U.S.C. § 1320a-7b(b)(1)-(2) (emphasis added).

In its opening brief, Novartis suggests that it lacked notice of the fact that the AKS proscribes the use of kickbacks to improperly influence pharmacy employees; it suggests, instead, that the AKS is solely concerned with improper influence on "a physician's medical judgment." *See* NPC Br. at 4. This assertion, which Novartis has repeated throughout the litigation, is simply disingenuous — cannot be squared with the AKS's text or on-point regulatory guidance issued by the Office of Inspector General for the Department of Health and Human Services ("HHS-OIG").[3]

First, the text of the AKS shows it is not limited to improper influence on "physicians." Instead, it applies to "*whoever*" solicits or receives kickbacks in return for referrals or recommendations and to the offer or payment of kickbacks to "any person" to induce recommendations. 42 U.S.C. § 1320a-7b(b)(1)-(2); *see also United States v. Vernon*, 723 F.3d 1234, 1254 (11th Cir. 2013) (the "plain language" of the AKS shows that its application "is not limited to payments to physicians who prescribe medication").

[3] For example, Novartis made this argument a key aspect of both in its initial motion to dismiss the Government's claims and its renewed motion to dismiss. [Dkt. 138, 203].

Moreover, as Judge McMahon explained in her May 29 decision, a 1994 Special Fraud Alert issued by HHS-OIG gave notice that the AKS prohibited using kickbacks to improperly influence pharmacy staff. *See* Memorandum Decision and Order dated May 29, 2014 ("*Novartis I*") at 33 [Dkt. 192]. That Alert, which was addressed to "prescription drug companies" like Novartis, highlighted kickback concerns raised by "marketing activities" directed at pharmacy staff that could interfere with their obligation to "recommend products in the best interest of the patient." 59 Fed. Reg. 65,372, at 65,376 (Dec. 19, 1994). Indeed, as Judge McMahon noted, the Alert "notified the public that it is illegal for a pharmaceutical company to *offer pharmacies remuneration* … in exchange for performing *'marketing tasks,'* such as *'sales-oriented educational or 'counseling' contacts* … or physician and/or *patient outreach*' when such acts occur in the course of pharmacy practice related to Medicare and Medicaid." *Novartis I* at 33 (citing 59 Fed. Reg. at 65,376) (emphasis added).

B. Novartis's Selective Summary Leaves Out Basic Features of the Exjade Kickback Scheme That Undercut Novartis's "Adherence" Requests

Novartis's brief purports to summarize the Government's allegations regarding the Exjade kickback scheme. *See* NPC Br. at 5, 7-8. It asserts that the Government deems the Exjade scheme to be in violation of the AKS because Novartis gave remuneration to BioScrip to "engage[] in 'intensive' adherence efforts." *Id*. at 7. Novartis also suggests that getting Exjade patients to order refills is always appropriate.[4] *See id*. at 5.

This is an inaccurate, self-serving depiction of how the Exjade scheme actually worked, leaving out basic features of the scheme that undercut the asserted relevance of Novartis's "adherence related" requests. As an initial matter, internal documents show that Novartis started the Exjade kickback scheme, which began in early 2007, not due to concerns about patient

[4] The article by John Porter that Novartis cites in support of this claim is one for which Novartis provided funding.

health, but in response to a "performance gap" between "actual" vs. "budgeted" Exjade sales. *See* Second Amended Complaint of the United States ("US SAC") at ¶¶ 253-256 [Dkt. 231]. In early 2007, Novartis saw that actual Exjade sales in January 2007 were significantly below its internal sales target. *Id*. at ¶ 253. To increase sales, Novartis sought to leverage BioScrip's ability to influence patients' decisions about whether to order Exjade refills. *Id*. at ¶¶ 255-256. Novartis did so by directly linking the number of patient referrals BioScrip received (having more patients resulted in higher revenue and more dispensing fees for BioScrip) to the level of refill orders BioScrip generated.[5] *See id*. at ¶¶ 256-271. Novartis also structured its rebate arrangement with BioScrip so that the rebate level was based on whether BioScrip generated enough Exjade orders to help Novartis meet its "National Exjade Sales Target ($)." *Id*. at ¶ 271.

Second, Novartis's brief also omits the fact Novartis and BioScrip both understood that their relationship was designed to have BioScrip promote Exjade refills in support of Novartis's marketing goals. *See id*. at ¶ 273. Thus, Novartis shared its internal marketing plans for Exjade with BioScrip, and BioScrip viewed its own "strategic plan" as "mirror[ing] and support[ing] Novartis priorities." *Id*. Indeed, the incentive system set up by Novartis achieved its desired effect — as a former BioScrip supervisor explained, BioScrip became "focused exclusively on the number of [Exjade] orders and refills, rather than on patient care." *Id*. at ¶¶ 284-288.

Third, Novartis's brief fails to acknowledge that it implemented this scheme even though it knew that Exjade patients did not always need refills. As internal Novartis documents show, by the time the Exjade scheme began in early 2007, Novartis already was aware that there were a number of appropriate reasons for patients to stop ordering refills — doctors frequently ordered discontinuation of treatment after patients experienced Exjade's side effects, and, as a Novartis

[5] As Novartis acknowledged, *see* NPC Br. at 6, and as detailed in the Government's complaint, Novartis controlled the distribution of Exjade patient referrals to BioScrip because it created an exclusive distribution system for Exjade called EPASS. *See* US SAC at ¶¶ 241-246.

executive acknowledged in an email, some patients stopped ordering refills "after several months" because they had "almost normalized iron values." *Id*. at ¶¶ 248-250. Further, as the scheme continued, more and more safety concerns were recognized, culminating in January 2010 with the requirement that the Exjade label feature a "black box warning." *Id*. at ¶ 238-239.

Finally, Novartis's brief leaves out the fact that those safety concerns did not affect how Novartis used kickbacks to induce BioScrip to recommend refills to Exjade patients. Instead, Novartis advised BioScrip to implement a refill program in which BioScrip employees were instructed to tell patients to keep on ordering refills without regard to whether the patients were experiencing side effects. *See id*. at ¶¶ 273, 284-292. Indeed, Novartis measured BioScrip's "performance" based exclusively on how long BioScrip was able to get Exjade patients to keep ordering refills. *Id*. at ¶ 286.

C. The Court's Prior Decisions on Motions to Dismiss

Novartis's brief fails to mention that Judge McMahon has issued two decisions denying Novartis's motions to dismiss the Government's claims and the holdings from those decisions are directly applicable to Novartis's current application. *See Novartis I* at 13-15, 41-43; *see also* Memorandum Decision and Order dated August 7, 2014 ("*Novartis IV*") at 12-13[Dkt. 227]. First, Novartis does not explain that the Court recognized that the 1994 HHS-OIG Special Fraud Alert gave drug-makers clear notice to the kickback issues raised by giving inducements to pharmacies to promote their drugs. *See supra* at 5.

Second, Novartis also fails to acknowledge that Judge McMahon's August 7 decision rejected an argument that Novartis is trying to resurrect as part of this motion. In its motion to dismiss, Novartis argued that it is liable only if "[its kickback] scheme succeeded in achieving its goal — *i.e.*, where a pharmacy convinced a physician (in the case of Myfortic) to prescribe a drug that he would not have otherwise prescribed, or convinced a patient (in the case of Exjade)

to order a refill that he would not have otherwise ordered." *Novartis IV* at 13. Judge McMahon squarely rejected this contention, concluding that, under Second Circuit law, Novartis has liability for the Myfortic and Exjade claims submitted by pharmacies that took kickbacks for promoting those drugs, irrespective of whether the kickback-tainted recommendations were the "but for" cause for patient being switched to Myfortic or ordering an Exjade refill. *See id*. at 13-19. As explained below, *see infra* at 17-18, this holding directly refutes Novartis's argument here that discovery about treatment protocols and other clinical information from federal health programs and facilities liability is relevant to whether the kickback-tainted recommendations made by pharmacies were the "but for" cause of the drug shipments. *See* NPC Br. at 16-20.

D. The Government's Document Productions and Novartis's Motion to Compel

To date, the Government has produced over 900,000 pages of documents to Novartis. Those include non-privileged records from the pre-suit investigation, such as transcripts and third-party document productions, administrative records from HHS-OIG relating to regulatory guidance on the AKS, and drug label information from the Food and Drug Administration ("FDA"). The Government also has provided Novartis with Medicare and Medicaid claims data for Exjade, Myfortic, and Myfortic's competitor drugs.

Moreover, even with regard to the overbroad requests at issue here, the Government did not reflexively refuse to respond. Instead, during meet-and-confer calls, the Government sought to better understand the basis for those requests and find potential compromises by asking Novartis to explain how its broad requests related to the factual or legal issues at stake in this case. However, those efforts did not result in more specific explanations.[6]

[6] For example, the Government asked Novartis to explain the relevance of Requests 71-73, 80-82, and 89-92, which broadly seek documents concerning HHS programs relating in any way to "adherence." *See* Exhibit A to Sheth Declaration at 1-4, 8-10 [Dkt. 248-1]. Novartis did not offer a specific explanation, and instead asserted conclusorily that those requests are relevant to its "knowledge, willfulness, and intent," its "defenses such as lack of notice," and the

In its motion to compel, Novartis also does not offer any detail regarding how the federal programs are likely to be relevant to this case. While Novartis's brief mentions, in a footnote, one federal program, the Medication Therapy Management ("MTM") programs that Medicare regulations require Part D plan sponsors to have as part of their plans, *see* NPC Br. at 9 n.3, it fails to explain that the MTM program requirements are set forth in Medicare Part D regulations, *see* 42 C.F.R. § 423.153(d), or that the Centers for Medicare and Medicaid Services ("CMS"), the HHS component that contracts with Part D plan sponsors, offers a significant amount of publicly available information about this program on its public website.[7]

Indeed, even a cursory review of the governing regulations and the public information from CMS shows how attenuated the purported connection is between the MTM programs and the refill promotion program that Novartis induced BioScrip to implement using kickbacks. The basic differences include, for example:

- MTM programs are not designed and implemented by drug-makers like Novartis. Instead, Part D plan sponsors are responsible for submitting these programs to CMS for annual review and approval. *See* 42 C.F.R. § 423.153(d)(1), (3), (6); CMS, *Medicare Part D Medication Therapy Management Program 2009 Fact Sheet* at 1 (July 1, 2009) (the "*2009 MTM Fact Sheet*").[8]
- All MTM programs are required to include a group of services, such as an annual

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Government's understanding of adherence. *See* 3/21/14 Letter from Manisha Sheth at 3; 7/16/14 Letter from Ben O'Neil at 3 (Ex. Y and Ex. Z to Sheth Decl.). [Dkt. 248-25, -26]. Similarly, the Government also asked Novartis to explain what made a program like the "Script Your Future" campaign (referred to in Novartis's Request 96) – a non-condition-specific program sponsored by hundreds of corporate, non-profit, and governmental entities or causes – similar to the Exjade scheme. Novartis did not provide any explanation.

[7] Under Part D, CMS contracts with a number of plan sponsors to administer prescription drug plans. Each plan sponsor, in turn, subcontracts with pharmacies to dispense drugs to Medicare beneficiaries enrolled in the Part D plan sponsors' plans. *See* US SAC at ¶¶ 26-32.

[8] Available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html (last visited September 29, 2014).

comprehensive medication review and quarterly targeted reviews, that pharmacists or other qualified persons provide to participating beneficiaries. *See* 42 C.F.R. § 423.153(d)(1)(v)-(viii). "Adherence" related activities, by contrast, are not a required element of these programs. Instead, a plan sponsor *may* design its MTM program to provide such services. *Id.*; *see also 2009 MTM Fact Sheet* at 7 ("[a] program may be designed to include any type or combination of MTM interventions," with "[r]efill reminders" as one permissible type).

- The MTM programs do not involve any type of compensation, whether in the form of rebates or patient referrals, from drug-makers to pharmacies. *See* 42 C.F.R. § 423.153(d)(5). Rather, CMS directs the Part D plan sponsors to pay the pharmacists and other qualified providers based on the time and resources necessary to implement the services. *Id.*; *see also 2009 MTM Fact Sheet* at 7-9.

ARGUMENT

POINT I

AS THE PARTY DEMANDING DISCOVERY, NOVARTIS HAS THE BURDEN TO SHOW "THE NECESSARY CONNECTION" BETWEEN ITS REQUESTS AND THE CLAIMS AND DEFENSES AT ISSUE

Under Rule 26, a party "may obtain discovery into regarding any non-privileged matter that is relevant to any party's claim or defense." FED. R. CIV. R. 26(b)(1). However, while the scope of discovery is broad, it does not encompass "requests based on pure speculation that amount to nothing more than a 'fishing expedition' into actions … not related to the alleged claims or defenses." *Collens v. City of New York*, 222 F.R.D. 249, 253 (S.D.N.Y. 2004); *see also Tottenham v. Trans World Gaming Corp.*, 2002 WL 1967023, at *2 (S.D.N.Y. June 21, 2002) (discovery "is not intended to be a fishing expedition, but rather is meant to allow the parties to flesh out allegations for which they initially have at least a modicum of objective support"); *Surles v. Air France*, 2001 WL 1142231at *2 (S.D.N.Y. Sept. 27, 2001) ("the information sought by Defendant does not become relevant merely because Defendant speculates that it might reveal

useful material"). Further, having brought "a motion to compel," Novartis must "provide the necessary connection between the discovery sought and the claims or defenses asserted in the case." *287 Franklin Ave. Residents' Ass'n v. Meisels*, 2012 WL 1899222, at *4 (E.D.N.Y. May 24, 2012); *accord Freedman.*, 2014 WL 3767034, at *3 (the "burden of demonstrating relevance is on the party seeking discovery").

POINT II

NOVARTIS HAS FAILED TO EXPLAIN HOW ITS "ADHERENCE RELATED" REQUESTS ARE RELEVANT TO THIS CASE

Novartis's "adherence related" requests purport to require the Government to produce discovery about (*i*) "federal health-related programs and grants[] and other federal [] policies, activities, programs, plans, or initiatives" that Novartis characterizes as being "similar" to the Exjade scheme;" (*ii*) rulemakings by HHS pursuant to two health information privacy statutes that excluded prescription refill reminders from the definition of "marketing activities" under the information privacy laws; and (*iii*) the "budgetary impact of medication adherence," including a report issued by the Congressional Budgetary Office ("CBO"). *See* NPC Br. at 10-11.

At the outset, Novartis does not, and cannot, claim that federal programs relating to adherence is relevant because Novartis relied on information about those federal programs. Indeed, as Novartis concedes in its brief, it did not "model[]" its conduct in the Exjade scheme on any federal programs or initiatives. *See* NPC Br. at 10 n.5 (if Novartis *had* done so, then it would, itself, already have the information sought). Instead, Novartis offers two tortured theories as to the relevance of its "adherence related" requests.

A. Federal Programs Relating to Adherence Are Not Relevant Just Because Novartis Believes That the Government Conduct Is Similar to the Exjade Scheme

Novartis first asserts that these requests are relevant because whether the Government engages in "similar conduct" is "unquestionable relevant" to the legality of the Exjade scheme

and because it is Novartis's "belie[f]" that "the Government promotes conduct that is substantially same as the [Exjade scheme]." *Id*. at 9-11. Both of these premises are faulty.

First, Novartis does not, and cannot, offer any authority in support of its assertion that the operations of federal programs are "unquestionable relevant" to the legality of Novartis's conduct in the Exjade scheme. There is no "similar government conduct" exception in the text of the AKS, and it is axiomatic that the AKS does not apply to the Government. *See* 1 U.S.C. § 1 (unless otherwise specified, "the words 'person' and 'whoever' [in federal statutes] include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals"); *United States v. United Mine Workers of America*, 330 U.S. 258, 275 (1947) (recognizing that "statutes employing [the term person] will not ordinarily be construed" as referring to the United States); *United States* v. *Bidloff* , 82 F. Supp. 2d 86, 94 (W.D.N.Y. 2000) ("it is well established when the personal pronoun whoever appears in a federal statute it should not be understood to refer to the [United States] unless the statute expressly so provides"). Thus, how federal programs deal with adherence says nothing about whether the Exjade scheme was illegal under the AKS or the FCA.

Nor, of course, has Novartis shown any federal program that is at all similar to the Exjade scheme orchestrated by Novartis. Beyond a subjective "belie[f]," Novartis fails to offer any specific details to explain what makes any federal program "similar" to the Exjade scheme. *See* NPC Br. at 9-11. A discovery request "does not become relevant merely because Defendant speculates that it might reveal useful material," *Surles*, 2001 WL 1142231 at, *2; and Novartis must "produce [some] specific facts [] to support" its unfounded belief. *Spina v. Our Lady of Mercy Med. Ctr.*, 2001 WL 630481, at *2 (S.D.N.Y. June 7, 2001) (quoting *Contemporary Mission, Inc. v. U.S. Postal Svc.*, 648 F.2d 97, 107 (2d Cir. 1981)).

Here, Novartis's inability to explain – with any modicum of specificity – the relevance of its "adherence related" requests is especially telling. As Novartis acknowledges, it has been aware of the Government's investigation of the Exjade scheme for some time. *See* NPC Br. at 6 (discussing the pre-suit investigation after the *qui tam* relator filed this action in November 2011). Since January 2014, Novartis has had the Government's amended complaint and known exactly what features of the Exjade scheme are alleged to be in violation of the AKS and FCA. *Id*. at 7. In addition, during the parties' meet-and-confer sessions, the Government repeatedly asked Novartis for more specific explanations of what makes those federal programs relevant.

Indeed, insofar Novartis's brief mentions a particular federal program that it deems "adherence-related," *see* NPC Br. at 9 n. 3 (referring to the MTM program under Medicare Part D), publicly available information readily shows that there is no meaningful similarity between the MTM program and the Exjade scheme. As discussed above, the MTM programs are administered by Part D plan sponsors, not drug makers. Those programs are not required to have an "adherence" component. Lastly, the pharmacists providing services under MTM programs are not compensated by drug makers based on refill levels, but instead are paid by plan sponsors according to the time and resources they put into those services. *See supra* at 9-10 (citing 42 C.F.R. §. § 423.153(d) and the *2009 MTM Fact Sheet*).

With regard to the two rulemakings by HHS under the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320-d *et seq*. ("HIPAA"), and the Health Information Technology for Economic and Clinical Health Act of 2009, Novartis has offered *no* argument or factual support as to any similarity between those rulemakings and the Exjade scheme. In fact, neither rulemaking has anything to do with the AKS; rather, both rules were promulgated to clarify the *patient privacy* requirements under HIPPA. *See* 75 Fed. Reg. 40,868 (July 14, 2010); 78 Fed. Reg. 5,566 (Jan. 25, 2013). Thus, nothing about those rulemakings suggests that they in

any way permitted a drug-maker like Novartis to give a pharmacy patient referrals and rebates in exchange for recommending refills.[9]

Finally, Novartis's brief offers absolutely nothing to support why there is any similarity between the Exjade scheme and the subject matter of its requests for documents concerning the "budgetary impact" of medication adherence programs. There is no connection between the Exjade scheme and any such "budgetary impact" analysis. For Novartis to demand the budgetary analysis, thus, is a classic example of a discovery "fishing expedition."

In sum, Novartis has wholly failed to support its assertion regarding the Government engaging in "similar conduct" as the Exjade scheme. That failure "is fatal to [Novartis's] motion to compel." *Zanowic v. Reno*, 2000 WL 1376251, at *6 (S.D.N.Y. Sept. 25, 2000).

B. Having Admitted That It Did Not "Model[]" the Exjade Scheme on Any "U.S. Programs," Novartis Cannot Claim That Such Programs Are Relevant to Its Knowledge or Willfulness

Novartis concedes that it did not "model" its conduct in the Exjade scheme on any federal programs or initiatives. *See* NPC Br. at 10 n.5. Nonetheless, it asserts that discovery into such programs would be relevant to whether it committed "knowing and willful violation of the AKS and the FCA." *Id*. at 11. This is simply wrong.

Novartis's *scienter* turns on the extent to which it either had actual knowledge that the Exjade scheme violated the AKS or, even without actual knowledge, it deliberately ignored or recklessly disregarded the likelihood that the scheme was in violation of the AKS. *See* 31 U.S.C. § 3729(b)(1)(A) (defining "knowingly" for purposes of the FCA to include actual knowledge, deliberate ignorance, and reckless disregard); *see also United States v. Raymond & Whitcomb Co*., 53 F. Supp. 2d 436, 447 (S.D.N.Y. 1999) (recognizing that the FCA's knowledge standard

[9] The HITECH rulemaking specifies that any payment to a "covered entity" for providing a refill reminder to a patient must be "reasonably related to the [] entity's cost of making the communication." 75 Fed. Reg. at 40, 886.

is intended to apply to those who try to avoid liability by acting "like the proverbial ostrich who buried its head in the sand"). Thus, for purposes of determining *scienter*, a factfinder must assess evidence of what *Novartis knew* at the time that it engaged in the Exjade scheme and what steps *Novartis took* at that time to investigate any "red flag" raised by this scheme.

On the other hand, as numerous courts have held, evidence regarding the internal operations and views of federal agencies is not relevant to a defendant's *scienter* unless the defendant knew and relied on such information. *See U.S. ex rel. Stephens v. Prabhu*, 163 F.R.D. 340, 343 (D. Nev. 1995) (rejecting FCA defendants' demand for discovery into government operations that was unknown to them at the time of the fraud because they "are seeking the records to create a knowledge defense that is three years too late"); *SEC v. Bankatlantic Bancorp, Inc.*, 285 F.R.D. 661, 668 (S.D. Fla. 2012) (documents in SEC's files "cannot provide probative information" about the securities fraud defendants' intent); *United States v. Elsass*, 2011 WL 3900846, at *5 (S.D. Ohio Sept. 6, 2011) ("Even assuming that actions or positions taken by IRS employees are relevant to the defenses of reasonable cause and willfulness, it is only those actions or those positions of which Defendants had actual knowledge that would be relevant"). Thus, Novartis – having disclaimed that it knew or relied on how federal programs operated when it orchestrated the Exjade scheme – cannot then claim its discovery requests regarding those programs are relevant to its knowledge or willfulness.[10]

In this regard, *U.S. ex rel. Finney v. Nextwave Telecom, Inc.*, 337 B.R. 479 (S.D.N.Y. 2006), the only authority cited by Novartis, simply does not support Novartis's contention. In *Finney,* the crux of the relator's alleged fraud was that "defendants violated the FCA by failing to bring a federal statute to the attention of the federal government in the course of a litigation to

[10] Indeed, as the Ninth Circuit recognized, to hold otherwise would create the problem of giving *carte blanche* to FCA defendants to create *post hoc* rationalizations to avoid liability. *See United States ex rel. Oliver v. The Parsons Co.*, 195 F.3d 457, 463 n.3 (9th Cir. 1999).

which the [G]overment was a party." *Id*. at 487. As Judge McMahon noted, this theory was "patently absurd." *Id*.

Here, the Government's Exjade claims do not allege any failure by Novartis to disclose a weakness of a legal theory in litigation, but that Novartis used patient referrals and rebates to induce a pharmacy to recommend Exjade refills. As Judge McMahon noted in *Novartis I*, HHS-OIG's regulatory guidance made clear that such conduct is illegal under the AKS. *Id.* at 33. Thus, unlike in *Finney*, Novartis cannot point to any "unresolved disputes about the proper interpretation of a statute or regulation." 337 B.R. at 488. Instead, this case is much closer to *Visiting Nurse Ass'n of Brooklyn v. Thompson*, 378 F. Supp. 2d 75 (E.D.N.Y. 2004), which Novartis mentions but fails to analyze, let alone distinguish. *See* NPC Br. at 11. As the court held in that case, a defendant cannot act contrary to what regulatory guidance indicates is required by a federal statute, certify its compliance with the statute, and then expect to escape FCA liability by disputing, after the fact, the validity of the regulatory guidance. *See Visiting Nurse Ass'n*, 378 F. Supp. 2d at 95-96. Accordingly, Novartis has failed to show that its "adherence related" requests are relevant to its *scienter*.[11]

POINT III

NOVARTIS HAS FAILED TO SHOW THAT ITS REQUESTS FOR CLINICAL PROTOCOLS AND RELATED DOCUMENTS FROM FEDERAL HEALTH PROGRAMS AND FACILITIES ARE RELEVANT

Through several exceptionally broad requests, Novartis also demands production of clinical protocols from practically all federal health programs and facilities relating to the treatment of kidney transplant patients and the administration of Exjade. *See*, *e.g.*, Request 19 (seeking "*[a]ll documents* reflecting or relating to *any Treatment Protocol for kidney transplants*

[11] In a footnote, Novartis also makes a half-hearted attempt to assert that these requests are relevant to whether its conduct was "consistent with industry standard." NPC Br. at 10 n.5. This argument is similarly unavailing. Indeed, Novartis's own compliance policies recognized that "[t]he fact that a particular arrangement is common in the health care industry is not a defense." *See* First Amended Complaint in Intervention of the Intervening States at ¶ 73 [Dkt. 257].

performed *at any hospital* operated by the United States"); Request 95 (seeking "[d]ocuments relating to the administration of Exjade … created or developed by … (i) the Department of Veteran Affairs ("VA"), including … any [] hospital or other healthcare facilities operated by the VA; (ii) the Department of Defense ("DOD"); (iii) the Office of Personnel Management ("OPM"); and/or (iv) HHS") (Ex. A to Sheth Decl. at 1, 15) [Dkt. 248-1]. Novartis claims that such discovery – which has no connection to the kickback schemes at issue or Novartis's *scienter* – are somehow relevant for two reasons.

First, it asserts that protocols from federal programs and facilities can show that the purported justifications offered by pharmacies like BioScrip or Transcript for their kickback-tainted recommendations were clinically acceptable. *See* NPC Br. at 16-18. According to Novartis, the clinical acceptability of the purported justification "bear[s] directly" on whether pharmacies made kickback-tainted recommendations to doctors to switch patients to Myfortic or to patients to order Exjade refills. *Id*. at 18.

Novartis's reasoning seems to be that if the federal agencies' documents show there is some clinical validity to the purported "justifications" for the pharmacies' recommendations, then such recommendations could not have been tainted by kickbacks. This argument defies logic. A pharmacy receiving kickbacks for recommending a drug has no incentive to disclose that its recommendations are part of a kickback scheme — such disclosure would undermine the efficacy of the scheme. Instead, the pharmacy has every incentive to provide purported justifications that sound clinically acceptable and seem legitimate. But the use of a clinically acceptable justification does not remove the taint of the kickback from a recommendation pursuant to a kickback scheme. Thus, the Court should reject this deeply illogical theory as to why clinical protocols at federal facilities are relevant.

Novartis also argues that discovery into those clinical protocols is relevant, claiming that this could allow it to "substantially undermine the U.S.'s contention that alleged 'switches' to Myfortic were the result of the efforts of financially incentivized pharmacists rather than the independent medical judgment" of the physicians." NPC Br. at 19. However, as discussed above, *see supra* at 7-8, Novartis argued and lost this very point in its motion to dismiss. *See Novartis IV* at 13 (rejecting Novartis's argument that an AKS violation requires that "a pharmacy convinced a physician [] to prescribe a drug that he would not have otherwise prescribed"). In denying that motion, Judge McMahon rejected Novartis's argument. *See id*. at 13-19; *see also Novartis I* at 33-34.

It is telling that Novartis' brief nowhere mentions this aspect of these prior decisions. *See supra* at 7-8. Novartis is trying to re-litigate an issue that Judge McMahon has considered and rejected. The Court should reject this entreaty and deny Novartis's motion insofar as it seeks discovery into treatment protocols used by federal health programs and facilities.[12]

POINT IV

IN LIGHT OF THE LACK OF RELEVANCE OF NOVARTIS'S REQUESTS, NOVARTIS IS NOT ENTITLED TO IMPOSE ON THE GOVERNMENT THE SUBSTANTIAL BURDEN TO RESPOND

Finally, while Novartis's failure to meet its "burden of demonstrating relevance" alone supports denial of its motion to dismiss, *Freedman*, 2014 WL 3767034, at *3, its motion also should be denied because the discovery burden that Novartis seeks to impose on the Government through its overbroad requests significantly outweighs any relevance to the claims and defenses

[12] As part of this argument, Novartis also seriously mischaracterizes what the Government said in court about the Exjade scheme. *See* NPC Br. at 19-20. As the transcript of the March 14, 2014 conference shows, the Government explained that "*Novartis itself was aware*" doctors were frequently directing patients to discontinue Exjade therapy due to side effects. *See* Ex. B to Sheth Decl. at 29:19-30:4 (emphasis added). Novartis's own awareness was critical because it shows why it gave kickbacks to BioScrip to recommend Exjade refills. How federal health program or facilities administered Exjade will not shed light on this issue. Similarly, Novartis fails to demonstrate the relevance of documents concerning any federal health program's relationship with BioScrip would shed any light on the claims or defenses in this case.

at issue in this case. *See* FED. R. CIV. P. 26(b)(2)(C)(iii). Under Rule 26(b)(2)(C), this Court "has broad discretion to limit discovery" if "the burden or expense outweighs the benefits of the discovery." *Scott v. Chipotle Mexican Grill, Inc*. 300 F.R.D. 188 (S.D.N.Y. 2014). Indeed, "even if the sought-after documents are relevant, the court may limit discovery" where "the burden … of the proposed discovery outweighs its likely benefit considering the needs of the case and importance of the documents." *Fort Worth Employees' Retirement Fund v. J.P. Morgan Chase & Co*., 297 F.R.D. 99, 102 (S.D.N.Y. 2013) (*Francis, J.*).

Here, Novartis's overbroad requests, by their own terms, purport to require a wide range of federal agencies and healthcare facilities to devote substantial time, personnel, and other resources to conduct searches based on nebulous concepts. *See*, *e.g.*, Request No. 19 (seeking "*[a]ll documents* reflecting or relating to *any Treatment Protocol for kidney transplants* performed *at any hospital* operated by the United States"); Request No. 80 (seeking "[d]ocuments relating to policies, activities, programs, plans, or initiatives developed by HHS … that *relate to adherence*") (emphasis added); (Ex. A to Sheth Decl. at 1, 8) [Dkt. 248-1].

Yet, as explained above, the relevance of the discovery sought by Novartis is dubious in light of the governing legal standards enunciated in Judge McMahon's prior decisions and the relevant allegations. Moreover, Novartis has offered no basis – except for its subjective beliefs and speculations – to conclude that its requests are likely to lead to discovery of relevant and admissible evidence. *See*, *e.g.*, NPC Br. at 9 (Novartis "believes the Government promotes conduct that is substantially the same as the conduct it seeks to penalize here.").

The burden of responding to Novartis's unduly expansive requests "outweigh[s]" the "likely benefits" of such discovery." FED. R. CIV. P. 26(b)(2)(C)(iii). Accordingly, the Court should deny Novartis's motion to compel on this ground as well. *See Chipotle Mexican Grill*,

300 F.R.D. at 188; *Viacom Int'l Inc. v. Youtube Inc*., 253 F.R.D. 256, 262-63 (S.D.N.Y. 2008); *Macmillan, Inc. v. Fed. Ins. Corp*., 141 F.R.D. 241, 242-43 (S.D.N.Y. 1992).

CONCLUSION

For the reasons set forth above, the Court should deny Novartis's motion to compel in its entirety.

Dated: September 29, 2014
New York, New York

Respectfully submitted,

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